

May 12, 2004

Division of Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: Registration of Food Facilities Under the Public Health Security

and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period **Docket No. 2002N-0276** 

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Reopening of Comment Period **Docket No. 2002N-0278** 

Dear Sir or Madam:

The Vinegar Institute (VI) is an international trade association representing manufacturers and bottlers of vinegar and suppliers to this industry. VI submits the following comments on the Food and Drug Administration's (FDA) notices published in the April 14, 2004, *Federal Register* soliciting comments regarding the Agency's interim final rules covering registration of food facilities and prior notice of imported foods (69 *Federal Register 19766*).

## Registration of Food Facilities

The Agency requested comments and submission of data or other information regarding the costs to a foreign facility of hiring a U.S. agent. We have been advised that the fee to register a foreign facility charged by some U.S. agents is \$445.00 for a single facility and \$150.00 for each additional facility. The economic impact of these costs is greater for foreign facilities that export small quantities of food products to the United States. We hope you find this information of use.

## **Prior Notice of Imported Food**

There have been a few issues noted regarding the FDA's Prior Notice System Interface (PNSI). There is no appropriate classification in the list of food product codes for industrial ethanol. In review of the Product Code Builder, there is no application for the use of ethanol in food production. We would be interested in being advised of the correct food product code for ethanol that is being imported into the U.S for food uses. This will allow importers to provide the Agency with the correct information. In addition, the software's archive of previously submitted prior notices does not appear to be functioning.

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We appreciate your consideration of these comments.

Sincerely,

Patricia Faison Technical Manager